



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/384,900	08/27/1999	ALVARO J. LAGUNA	MP/147	8440

28596 7590 02/09/2005

GORE ENTERPRISE HOLDINGS, INC.
551 PAPER MILL ROAD
P. O. BOX 9206
NEWARK, DE 19714-9206

EXAMINER

MENDEZ, MANUEL A

ART UNIT	PAPER NUMBER
----------	--------------

3763

DATE MAILED: 02/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.



UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
P.O. Box 1450
ALEXANDRIA, VA 22313-1450
www.uspto.gov

MAILED

FEB 09 2005

GROUP 3700

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 09/384,900
Filing Date: August 27, 1999
Appellant(s): LAGUNA ET AL.

David J. Johns
Reg. No. 31,527
W.L. Gore & Associates, Inc.
551 Paper Mill Road
P.O. Box 9206
Newark, DE 19714-9206
(928) 864-4800
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed on September 14, 2004.

(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is correct.

(4) *Status of Amendments After Final*

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) *Summary of Invention*

The summary of invention contained in the brief is correct.

(6) *Issues*

The appellant's statement of the issues in the brief is correct.

(7) *Grouping of Claims*

Appellant's brief includes a statement that claims 24-42 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

(8) *Claims Appealed*

The copy of the appealed claims contained in the Appendix to the brief is correct.

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 24-26 are rejected under 35 U.S.C. 102(b) as being anticipated by **Daneshvar (US 5,728,066)**. Daneshvar teaches a balloon that is slidable along a catheter (col. 3, lines 21-25). Daneshvar further teaches that the balloon does not leak between itself and the catheter that it is mounted on. (col. 9, lines 40-45).

Claims 24, 25, 29, 32-34, 37, and 40-42 are rejected under 35 U.S.C. 102(b) as being anticipated by **Kraus, et al., (US 5,718,680)**. Kraus teaches all the claimed subject matter including the balloon being attached to a non-distensible member (inner tube 21) to render the ends non-distensible, and that it can be made from polytetrafluoroethylene (PTFE); (col. 7, para 1).

Claims 28, 30, 31, 36, 38, and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Daneshvar in view of Crocker, et al., (US 5,843,116)**. This rejection is set forth in a prior Office Action, mailed on September 8, 2003.

Claims 27 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Daneshvar in view of Ravenscroft, et al., (US 5,766,201)**. This rejection is set forth in a prior Office Action, mailed on September 8, 2003.

(11) Response to Argument

The examiner of record acknowledges appellant's request that the grounds for rejection be considered against independent claim 24 alone. Accordingly, for the purposes of this appeal, claims 23-42 will stand or fall together with independent claim 24.

ANALYSIS

In relation to claim 24, the Appellant argues that the present invention as claimed differs from the prior art because the balloon sleeve of the present invention is rendered non-distensible prior to being formed into a balloon by mounting on the catheter shaft.

Claim 24 defines the present invention as follows:

A sleeve adapted to be mounted on a catheter shaft so as to be formed into an inflatable balloon comprising the sleeve having a first end, a second end, and a middle section; wherein **prior to being formed into the balloon** by mounting on the catheter shaft at least one of the ends is non-distensible while the middle section of the sleeve is distensible.

Chisum on Patents, Section 8.05, describes a product-by-process claim as one in which the product is defined at least in part in terms of the method or process by which it is made. The construction of claim 24, and specifically, the wherein clause stating "prior to being formed into the balloon by mounting on the catheter shaft" suggests that claim 24 must be considered and interpreted according to the guidelines for product-by-process claims.

Accordingly, case law has already defined the Guidelines for interpretation of product-by-process claims. The Court in *In re Thorpe* expressly concluded, "even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a

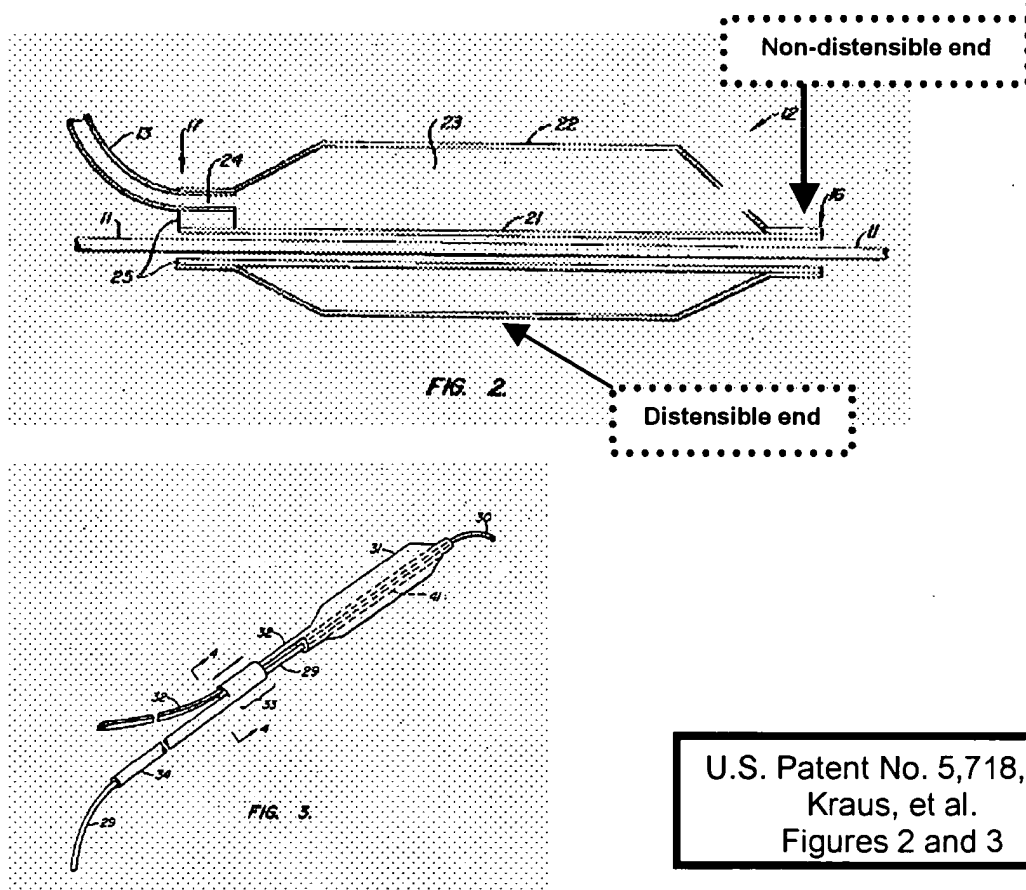
product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process".¹ Accordingly, with respect to claim 24, it is totally irrelevant that at least one of the ends of the sleeve is non-distensible prior to being formed into the balloon since the patentability of a product-by-process claim does not depend on the method of production, but rather in the structural characteristics of the final product.

In this particular case, according to the preamble of claim 24, the final product is a balloon catheter since the preamble recites essential structure that is necessary to give life, meaning and vitality to the claim.² Consequentially, for the purposes of patentability, the claim must be interpreted as a balloon catheter having a sleeve forming a balloon wherein at least one of the ends is non-distensible while the middle section of the sleeve is distensible.

A careful review of Daneshvar and Kraus, et al., suggests that both patents disclose a "balloon catheter having a sleeve forming a balloon wherein at least one of the ends is non-distensible while the middle section of the sleeve is distensible". Importantly, the Appellant agrees with this conclusion on page 4 of the Brief. In line 7, while discussing the teachings of the Daneshvar patent, the Appellant states, "any non-distensible ends that may be formed in this process will be created only after the sealed balloon is formed in conjunction with the center tubing" (emphasis added). Since the

¹ In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

evaluation of claim 24 should be focused on the characteristics of the final product, the creation in Daneshvar of distensible ends after the formation of the sealed balloon is clearly a characteristic of the final product that can be utilized as evidence to evaluate the patentability of claim 24. Therefore, since Daneshvar discloses a balloon catheter having a sleeve forming a balloon wherein at least one of the ends is non-distensible while the middle section of the sleeve is distensible, it must be reasonable to conclude that Daneshvar anticipates the subject matter of claim 24.



Concerning the merits of the rejection using Kraus, et al., figures 2 and 3 show a balloon catheter having a sleeve forming a balloon wherein at least one of the ends is

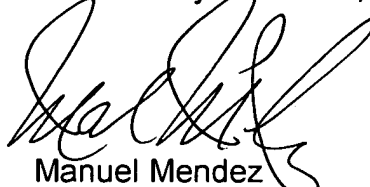
² Pitney Bowes, 51 USPQ2d at 1165-66; Kropa v. Robie, 88 USPQ 478, 480-481 (CCPA 1951).

U.S. Patent No. 5,843,116
Crocker, et al.
Figures 2 and 3

In figures 2 and 3, Crocker, et al., shows a balloon catheter having a sleeve forming a balloon wherein at least one of the ends is non-distensible (37,39) while the middle section of the sleeve is distensible (30). In view of these observations, Crocker, et al., anticipates the subject matter in claim 24. Concerning the merits of Ravenscroft, et al., it is respectfully noted that this patent also discloses a balloon catheter having a balloon with distensible and non-distensible sections. Therefore, since both patents disclose all the structural elements disclosed in claim 24, Appellant's arguments in the Brief should be considered non-persuasive.

For the above reasons, it is believed that the rejections should be sustained.

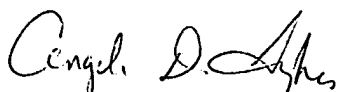
Respectfully submitted,



Manuel Mendez
Primary Examiner
Art Unit 3763

MM
January 31, 2005

Conferees



Ms. Angela Sykes
Supervisory Patent Examiner
AU 3762



Mr. Nicholas D. Lucchesi
Supervisory Patent Examiner
AU 3763

GORE ENTERPRISE HOLDINGS, INC.
551 PAPER MILL ROAD
P. O. BOX 9206
NEWARK, DE 19714-9206